

REMARKS

Claims 1, 3-13, 17-20, 22-23, 28 and 30-31 were presented for examination. The Patent Office notes that all but Claim 31 were examined. Claims 1 and 7 are amended. Claims 1, 3-13, 17-20, 22-23, 28 and 30-31 remain in the Application.

The Patent Office rejects Claims 1, 5-7, 17-19 and 28 under 35 U.S.C. §102(e). The Patent Office finds Claims 3-4, 8-13 and 30 allowable over the prior art of record. No indication is given of the status of Claims 20, 22-23 and 31.

Reconsideration of the all the pending claims is respectfully requested in view of the above amendments and the following remarks.

A. 35 U.S.C. § 102(e): Rejection of Claims 1, 5-7, 17-19 & 28

The Patent Office rejects Claims 1, 5-7, 17-19 and 28 under 35 U.S.C. §102(e) as anticipated by U.S. Patent Application 2003/0212453 of Mathis, et al. (Mathis). Mathis discloses a mitral valve therapy device that may be deployed in the coronary sinus and the coronary sinus re-shaped to affect the geometry of the mitral valve. As shown in Mathis, device 30 includes elongated body 32 having systole anchor 34 and proximal anchor 36. Device 30 may be formed from Nitinol or stainless steel. See, page 4, para. [0048]. Proximal anchor 36, when deployed, is configured to permit proximal movement. See, page 4, para [0048]. Systole anchor 34 includes elongated fixation member 38 that is hingedly coupled to a distal end of device 30 at hinge 40. Fixation member 38 includes support 42 that is hingedly connected to fixation member 38 at hinge point 44. A proximal end of fixation member 38 includes loop 46 which is looped about device 30 to permit the loop to slide along the device. Loop 46 forms part of a lock for locking anchor 34. See, page 4, para. [0051].

The deployment system 50 illustrated in FIG. 2 includes an elongated catheter 52, an elongated pusher 54 and a tether 56. In deploying the device 30, the tether 56 is first looped about the proximal anchor 36 of the device 30 as illustrated and the device is then loaded into catheter 50. The tether is then threaded through an internal lumen 58 of the pusher 54 and looped around the proximal anchor 36 of the device as illustrated. The pusher is then advanced along the tether 56 for engaging

the device 30 and pushing the device systole to the catheter to a predetermined position at the distal end of the catheter 50. The catheter with the device 30 loaded therein is fed into the heart and into the coronary sinus ostium 30 into the coronary sinus to place the catheter in a position such that device 30 is adjacent and micro valve annulus. Thereafter, the device is maintained in a stationary position by the pusher 54 as the catheter 50 is partially withdrawn to expose the distal anchor 34. Once the distal anchor is exposed, it is deployed by the catheter in a manner to be described more particularly with respect to FIGS. 3-6. Once the distal anchor 34 is deployed, the catheter 50 is then retracted proximally of the anchor 36. This exposes the proximal anchor and permits the proximal anchor to self-deploy. Once the proximal anchor is deployed, the tether 56 is pulled proximally to move the proximal anchor 36 in a proximal direction for tightening the device within the coronary sinus and to an extent which results with desired effect on the geometry of the micro valve annulus 20. . . . When the device 30 is in its final position within the coronary sinus 14, the pusher 54 and catheter 50 may be removed from the heart. The tether 56 may be permitted to remain in the heart during an acute phase to ascertain the effectiveness of the device 30. Should further adjustment of the device be necessary, the tether 56 may then be used as a guide for guiding the introduction of the catheter 50 back into the heart. Page 4, para. [0049].

The Patent Office characterizes Mathis as disclosing tether 56, aptation device 52 coupled about an axis of the tether, and fastening member 36 coupled to the tether including projection 48. As is clear from the above discussion, tether 56, catheter 50/52, and pusher 54 are not part of device 30, but serve to position device 30.

Independent Claim 1 describes an apparatus comprising a tether; a deformable aptation device coupled about an axis of the tether at a position corresponding to a location to contact cusps of an atrioventricular valve during systole; and a fastening member coupled to the tether at a position distal to the aptation device. The aptation device is deformable in response to forces applied to the aptation device by cusps of an atrioventricular valve.

Independent Claim 1 is not anticipated by Mathis, because Mathis does not describe an apparatus including a tether, an aptation device coupled about an axis of the tether that is deformable in response to forces applied to the aptation device by cusps of an atrioventricular valve. Mathis discloses catheter 50/52 that the Patent Office characterizes as an aptation device. There is no indication in Mathis that catheter 50/52 is deformable in response to forces applied to

it by cusps of an atrioventricular valve. Catheter 50/52 is used to deploy device 30, nothing further. Details about the composition of catheter 50/52 are not provided in Mathis.

Claims 5-7, 17-19 and 28 depend from Claim 1 and therefore contain all limitations of that claim. For at least the reasons stated with respect to Claim 1, Claims 5-7, 17-19 and 28 are not anticipated by Mathis.

Applicant respectfully requests that the Patent Office withdraw the rejection of Claims 1, 5-7, 17-19 and 28 under 35 U.S.C. §102(e).

B. Allowable Subject Matter

The Patent Office indicates Claims 3-4, 8-13 and 30 are allowable over the prior art of record. The Patent Office does not give any indication of the allowability of Claims 20, 22-23 and 31. Applicants believe the claims likewise are allowable.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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Date: 8/10/07

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